



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/531,965 | 11/07/2005 | Stefan Golz | Le A 36 374 | 8345 |
| 35969 7590 02/19/2009 Barbara A. Shimei Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591 | | | | |
| EXAMINER | | | | |
| SHEN, BIN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1657 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 02/19/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,965

Applicant(s)

GOLZ ET AL.

Examiner

BIN SHEN

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- _____ Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- _____ Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 Nov. 2008 has been entered.

Status of the Claims

Claims 2, 27, 28 are considered on the merits.

In view of the amended claims, the rejection under 35 USC § 102(b) is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujishige et al. (1999).

Fujishige et al. teach a method of determining the activity of a PDE 10A polypeptide at a certain concentration and at a different concentration of several test compounds (page 18443, right column, last paragraph and Table II). Table II shows the IC50 value of the tested compounds/inhibitors. A test compound (inhibitor) needs to be tested at several different concentrations in order to obtain an accurate IC50 value. The method also identifies test compound as a potential therapeutic agent useful in the treatment of cardiovascular disease, and

other diseases involve the tissue/organ where PDE 10A is expressed, (see expression of human PDE 10A in various tissues such as heart that related to cardiovascular disease and brain that related to Alzheimer's disease, on page 18442, Fig. 3) because the only nexus between PDE 10A and various diseases claimed in the specification is the tissue specific expression patterns which is shown by Fujishige in Fig.3 on page 18442.

Fujishige does not teach determining whether the test compound has an effect on a symptom of the cardiovascular disease/Alzheimer's disease in an in vivo assay.

However, Fujishige suggest a link between the tissue specific expression pattern of PDE10A and genetic disease (such as juvenile Parkinsonism, see page 18445, left column, end of 1st full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Fujishige to determine whether the test compound has an effect on a symptom of the diseases (cardiovascular/Alzheimer's, etc.) involved in the tissue/organ where PDE10A expresses because Fujishige teaches a method of screening for therapeutic agents (read as inhibitors) that affect PDE10A activity and identify the compound (inhibitor) as potential therapeutic agent useful in the treatment of diseases by showing PDE10A's tissue specific expression pattern. One would have been motivated to use the method to determine whether the test compound has an effect on a symptom of cardiovascular/Alzheimer's diseases because Fujishige et al. specifically described the link between PDE10A expression pattern and genetic disease (page 18445, left column, end of 1st full paragraph), and would reasonably have expected success in view of Fujishige's suggestion of analysis of tissue distribution in detail for pharmacological analysis using selective inhibitors to elucidate its physiological role (page 18445, left column, 2nd full paragraph).

It is obvious for a person of ordinary skill in the art at the time of the invention, upon reading the reference, to follow up the screening tests with animal and clinical trials to determining whether the test compound has an effect on a symptom of the diseases (such as cardiovascular/Alzheimer's disease whose tissue is related with the expression pattern of the expression/inhibition pattern) with anticipated success because a person of ordinary skill has good reason to pursue the known options within his/her technical grasp to determining if the test

compound has an effect on a symptom of the cardiovascular/Alzheimer's disease (because their tissue expression pattern are related as taught by Fujishige).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 11/24/2008 have been fully considered but they are not persuasive.

Applicant argues that Fujishige does not expressly or inherently describe a step of determining whether the test compound has an effect on a symptom of the recited disease in an in vivo assay.

It is the examiner's position that Fujishige teaches all the steps in the claimed screening method, and it is obvious for a person of ordinary skill in the art, upon reading the reference, to recognized the desirability of determining whether the test compound has an effect on a symptom of disease in an in vivo assay because the physiological roles of the selected inhibitors are routinely tested in in vivo animal model (as Fujishige suggest to test the role, see page 18445, left column, 2nd full paragraph), thus it is within the technical grasp of a person of ordinary skill in the art to do the in vivo test with anticipated success from the in vitro test results as reported by Fujishige.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-

9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

B Shen

Art Unit 1657

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657